

KO13998

FEB 13 2002

## 510(k) SUMMARY

Submitted For: **SHEEN MORE ENTERPRISE CO., LTD.**  
**No. 16 Tou Kung Six Road**  
**Tou-Liu Expanded Industrial Park**  
**Tou-Liu City, Yun-Lin County**  
**Taiwan R.O.C.**

Submitted By: **TUCKER & ASSOCIATES**  
Official Correspondent for SHEEN MORE ENTERPRISE  
CO., LTD.  
**JANNA P. TUCKER**, President-CEO  
198 Avenue de la D'emerald  
Sparks, NV 89434-9550  
Phone: 775-342-2612  
Fax: 775-342-2613  
E-Mail: [Tuckerjan@aol.com](mailto:Tuckerjan@aol.com)

Date of Submission: 29 November 2001

Device Name: **POWDER-FREE LAVENDER/PURPLE NITRILE  
EXAM GLOVES**, Class I Device, 80LZA

Proprietary Name: (Multiple Labels) Powder-Free Lavender/Purple Nitrile  
Exam Gloves.

Labels/Labeling: This device will be marketed to healthcare professionals at  
Dentist and Doctor Offices, Laboratories, Clinics and  
Hospitals through its distributors for the intended use.

Intended Use: A patient examination glove is a disposable device intended  
for medical purposes that is worn on the examiner's hand  
or finger to prevent contamination between patient and  
examiner.

Substantial Equivalence: Both in its intended use and/or physical  
characteristics, this device is equivalent to devices  
currently marketed by U.S. companies. Except for color, it  
is **substantially Equivalent** to the device manufactured by  
Sinochem Ningbo Latex Glove Factory's K980802 glove  
and Ningbo Yujiang's Lavender/Purple Nitrile Glove  
(K003563).

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Test Results (Means  
and/or Successful  
Results:

This device has met or exceeded the following  
standards and/or tests:

ASTM D 3578-00  
ASTM D 5712-00  
ASTM D 6124-00  
ASTM D 5151-00  
ASTM F 1671  
ASTM F 1383  
ASTM F 903

Bio-Compatibility:

Dermal Sensitization  
Primary Skin Irritation

Conclusion:

This device is substantially equivalent to the devices  
Approved as K980802 and K003563.

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## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Sheen More Enterprise Company Limited  
C/O Janna P. Tucker  
Consultant  
Tucker & Associates  
198 Avenue De La D'Emerald  
Sparks, Nevada 89434-9550

Re: K013998

Trade/Device Name: Powder-Free Lavender/Purple Nitrile Exam Gloves  
Regulation Number: 880.6250  
Regulation Name: Patient Examination Gloves  
Regulatory Class: I  
Product Code: LZA  
Dated: November 29, 2001  
Received: December 4, 2001

Dear Ms. Tucker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

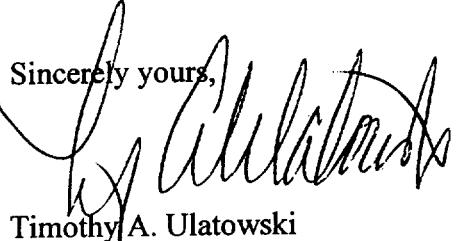
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski

Director

Division of Dental, Infection Control  
and General Hospital Devices

Office of Device Evaluation

Center for Devices and  
Radiological Health

## INDICATIONS FOR USE

**APPLICANT:** SHEEN MORE ENTERPRISE CO., LTD.

**510(k) NUMBER:** K 01 3998

**DEVICE NAME:** POWDER-FREE LAVENDER/PURPLE NITRILE EXAM GLOVES

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Chris S. Lin

(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K 01 3998